The opinion in support of the decision being entered today was **not** written for publication and is **not** binding precedent of the Board.

Paper No. 18

UNITED STATES PATENT AND TRADEMARK OFFICE

_____

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

_____

Ex parte ANDREW W. BUIRGE, PAUL J. BUSCEMI
and PAUL H. BURMEISTER

_____

Appeal No. 2000-0673
Application No. 08/960,276

_____

ON BRIEF

_____

Before CALVERT, COHEN, and FRANKFORT, Administrative Patent Judges.

CALVERT, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal from the final rejection of claims 55 to 59. Claim 61, the other claim remaining in the application, has been allowed.

The subject matter in issue is defined by claim 55, the only independent claim on appeal, as follows:

55. A method of applying a collagen coating on an expandable stent, wherein the expandable stent has a metal surface, comprising the step of, coating the metal surface with collagen by electrodeposition, wherein the expandable stent is expandable from a collapsed delivery diameter to an expanded deployment diameter, such that the delivery diameter is reduced from the deployment diameter.

The appealed claims are reproduced in the appendix of appellants' brief.

The references applied in the final rejection are:

Vieth et al. (Vieth)	3,758,396	Sep. 11, 1973
McNamara et al. (McNamara)	5,147,370	Sep. 15, 1992
Shirkanzadeh	5,205,921	Apr. 27, 1993

The claims on appeal stand finally rejected under 35 U.S.C. § 103(a) on the following grounds:

(1) Claims 55 to 57 and 59, unpatentable over McNamara in view of Vieth.

(2) Claim 58, unpatentable over McNamara in view of Vieth and Shirkanzadeh.

Rejection (1)

McNamara discloses an expandable stent made of nickel/titanium metal alloy (Nitinol). At col. 5, lines 1 to 20, the reference teaches that the stent may be coated with

various materials including, inter alia, collagen (line 17).

Vieth discloses a method of depositing an enzyme and a carrier, such as collagen (col. 3, lines 72 and 74), on an electrically conductive support by means of electrodeposition, the support acting as the cathode in a conductive medium containing the enzyme and carrier. The examiner takes the position that (answer, page 3):

> It would have been obvious to one having ordinary skill in the art to have utilized the method of electrodeposition as taught by Vieth et al to coat the stent of McNamara et al for an even coverage over the stent.

After fully considering the record in light of the arguments presented in appellants' brief and reply brief, and in the examiner's answer, we consider that the rejection is well taken.

Appellants argue that there would have been no suggestion or motivation for one of ordinary skill in the art to have combined the references, noting that Vieth is not directed to stents or implantable medical devices, that Vieth's process may involve using impure materials not suitable for implantation, and that Vieth indicates that there may be degradation of the coating. These arguments are not

persuasive. In our view, one of ordinary skill would have found ample suggestion to electrically deposit the collagen coating of McNamara in Vieth's teaching that (col. 2, lines 72 to 75):

> A unique advantage of the process of the present invention is that pre-shaped electrodes may be used, thus enabling uniform distribution of the immobilized enzyme-membrane complexes on irregularly shaped supports.

Since the stent disclosed by McNamara is a helix, i.e., an "irregularly shaped" support, this disclosed advantage of the Vieth process would have motivated one of ordinary skill to select that process for coating the McNamara stent. Moreover, as the examiner notes, Vieth discloses in Example 2 the coating of a stainless steel wire helix which, although considerably larger than a stent, would have suggested using the Vieth process to coat other helically-shaped objects, such as the McNamara stent.

Appellants note that at col. 8, lines 58 to 60, Vieth states that the coating on the helix disintegrated after four runs. However, we do not consider that this would dissuade one of ordinary skill from electrodepositing the coating on the McNamara stent, given the above-discussed advantage

disclosed by Vieth and the fact that in Example 3, where the coating was deposited on flat stainless steel electrodes, Vieth discloses that, as compared to conventional casting, electrodeposited films "showed very little disintegration of the film, even after repeated use" (col. 9, lines 22 to 28).

Appellants also note that one purpose of the Vieth process was to allow the use of less pure materials, but in our view this is somewhat beside the point, since there is nothing in Vieth which precludes the use of electrodeposition for depositing pure materials, as would be used to coat the stent of McNamara. In fact, one of ordinary skill who intended to deposit a high-purity collagen coating containing a protein would be further motivated to use electrodeposition by Vieth's disclosure that the enzyme (protein) is purified during the electrodeposition process
(col. 7, lines 46 to 65).

Accordingly, we conclude that claim 55, as well as claims 56, 57 and 59 which appellants have grouped therewith (brief, page 5), are prima facie obvious over the combined teachings of McNamara and Vieth, and will sustain rejection (1).

Rejection (2)

Claims 56 and 58 read:

56. The method of claim 55 wherein the stent functions as a cathode in an anode/cathode pair and is immersed in an aqueous electrolyte solution including collagen and an electrical potential is established between the anode and cathode adequate to sustain electrodeposition of the collagen from the solution onto the metal surface of the stent.

58. The method of claim 56 wherein the potential is about 3 volts.

In discussing the voltage to be applied between the electrodes (the cathode being the item to be coated), Vieth states at col. 5, line 65 to col. 6, line 3:

> Voltage and current requirements are dependent upon the dimensional parameters of a given system, such as the area of the support to be coated, the distance between electrodes, the temperature, and the concentration of materials and electrolytes in the aqueous mixture. Generally, it is preferable to use a relatively low voltage supply, such as from about 10 to 100 volts. The actual current requirements are quite small, generally from 1 to 10 amperes. Working at low voltages avoids an undesirable increase in temperature, which may denature the enzyme or its carrier, and also tends to favor electrophoresis over electrolysis. Voltages for a given application can be readily determined by simple trial and error.

While the about 3 volts recited in claim 58 is lower than the voltage range disclosed by Vieth, supra, as generally preferable, we consider that it would have been obvious to use that voltage when electrodepositing collagen onto the stent of

McNamara. The 3-volt potential would naturally result from following the above-quoted teachings of Vieth that working at low voltages is desirable, and that "[v]oltages for a given application can be readily determined by simple trial and error" (col. 6, lines 1 to 3). It is well settled that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980). Appellants have submitted no evidence to show that the claimed 3-volt potential gives results which are "unexpectedly good." Id.

The examiner has cited Shirkanzadeh for its disclosure of a potential of 3 volts (col. 2, lines 35 to 37), but although the electrolyte may contain collagen (col. 3, line 12), the purpose of the process disclosed by Shirkanzadeh is, as appellants point out, the electrodeposition of ceramic coatings, such as oxide and phosphate coatings. In any event, however, we consider Shirkanzadeh to be essentially superfluous to the rejection of claim 58 for the reasons enumerated in the preceding paragraph.

Finally, on page 11 of the brief, appellants contend that

"the field of stent manufacturing and design is a crowded and highly competitive field," and quote the following sentence from Continental Can Co. USA Inc. v. Monsanto Co., 948 F.2d 1264, 1273, 20 USPQ2d 1746, 1752 (Fed. Cir. 1991):

> [W]hen differences that may appear technologically minor nonetheless have a practical impact, particularly in a crowded field, the decision-maker must consider the obviousness of the new structure in this light.

We note however that in the Court's opinion this sentence is followed by:

> Such objective indicia as commercial success, or filling an existing need, illuminate the technological and commercial environment of the inventor, and aid in understanding the state of the art at the time the invention was made. *See In re Piasecki,* 745 F.2d 1468, 1475, 223 USPQ 758, 790 (Fed. Cir. 1984) (secondary considerations "often establish that an invention appearing to have been obvious in light of the prior art was not" (quoting *Stratoflex, Inc. v. Aeroquip Corp.,* 713 F.2d 1530, 1538-39, 218 USPQ 871, 879 (Fed. Cir. 1983)).

Since appellants have not furnished any evidence[1] to show that the differences between the claimed invention and the prior

[1] Argument of counsel cannot take the place of evidence. In re Wiseman, 596 F.2d 1019, 1023, 201 USPQ 658, 661 (CCPA 1979).

art have a "practical impact," as by showing commercial success or other "objective indicia," the foregoing quotations from Continental Can are not considered relevant to the present case.

Rejection (2) will be sustained.

Conclusion

The examiner's decision to reject claims 55 to 59 is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

IAN A. CALVERT Administrative Patent Judge	)	
IRWIN CHARLES COHEN Administrative Patent Judge	)	BOARD OF PATENT APPEALS AND INTERFERENCES
CHARLES E. FRANKFORT Administrative Patent Judge	)	

IAC:lbg

OLIVER F. ARRETT
VIDAS ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE, SUITE 2000

MINNETONKA, MN 55343-9131